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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,585	01/13/2006	Robert S. Foote	DC0261US.NP	1514

26259 7590 12/31/2007

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
12/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,585.	FOOTE ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kikuta et al., (Increased plasma levels of B-type natriuretic peptide in patients with unstable angina, American Heart Journal, Vol 132, July 1996, pages 101-107).

Kikuta e al disclose a method of determining the level of B-type natriuretic peptide (BNP) in a plasma sample isolated from a patient diagnosed with unstable angina and comparing the level to a control (abstract, Fig 1, & pgs 101-103). Kikuta et al correlates the unstable angina with myocardial ischemia (p.104 & p. 106).

Regarding the interpretive "wherein" clause recited in claim1 ("wherein an increase in the level in the sample as compared to the control is indicative of cardiac ischemia in the individual ", the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results to those steps. Therefore, the "wherein" clause is not considered to further limit the method defined by

the claim and has not been given weight in construing the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

3. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Valkirs et al (US 2003/0109420).

Valkirs et al disclose a method of diagnosing myocardial ischemia in a patient. (pages 39-40). Valkirs et al disclose determining a level of B-type natriuretic peptide (BNP) in a sample isolated from a patient (p. 7, pgs 31-32 & 39-40). Valkirs et al disclose that the sample can be obtained after the induction of a stress test (p. 39 1st col). Valkirs et al disclose comparing the level to a control and correlating the result to myocardial ischemia. Valkirs et al disclose that the control is obtained prior to stress testing (p. 39, 2nd col). Valkirs et al disclose that when the test sample is greater than the control that a diagnosis of myocardial ischemia is made.

Regarding the interpretive "wherein" clause recited in claim1 ("wherein an increase in the level in the sample as compared to the control is indicative of cardiac ischemia in the individual ", the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results to those steps.

Therefore, the "wherein" clause is not considered to further limit the method defined by the claim and has not been given weight in construing the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

4. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Zoghbi et al (US 2004/0243010).

Zoghbi et al disclose determining the level of BNP in samples obtained from a patient. Zoghbi et al disclose determining the level of BNP in a sample from the patient prior to exercise to establish a baseline (control) and also teaches determining the level of BNP in a sample from the patient post exercise (abstract, pgs 9-10, particularly p. 10, Example 7). Zoghbi et al disclose that levels of BNP increased from baseline to post-exercise.

Regarding the interpretive "wherein" clause recited in claim1 ("wherein an increase in the level in the sample as compared to the control is indicative of cardiac ischemia in the individual ", the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results to those steps. Therefore, the "wherein" clause is not considered to further limit the method defined by

the claim and has not been given weight in construing the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

Conclusion

5. No claims are allowed.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

De Lemos et al (The New England Journal of Medicine, Vol 345, No. 14 2001, pages 1014-1021). Disclose the prognostic value of B-type natriuretic peptide in patients with acute coronary syndromes and teaches that BNP was measured in plasma of patients after the onset of ischemic symptoms (abstract).

Dahlen et al (US 2003/0022235) disclose the use of B-type natriuretic peptide as a prognostic indicator in acute coronary syndromes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gary Counts
Examiner
Art Unit 1641
December 21, 2007

LONG V. LE 12/21/07
SUPERVISORY PATENT EXAMINER
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